UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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Dear Dr. Thomson:

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Thank you for the opportunity to participate in the Australian Senate's Rural and Regional Affairs and Transport References Committee for inquiry and report. I am responding on behalf of Unites States Environmental Protection Agency's Acting Administrator, Andrew Wheeler because my office is responsible for regulating pesticides in the United States.

Like you and your colleagues, we are committed to providing farmers timely access to safe, environmentally sustainable and productivity enhancing products. While, we cannot speak on Australian Pesticide and Veterinary Medicines Authority's processes for reviewing and reassessing the safety of agricultural chemicals, we can describe the U.S. Environmental Protection Agency's processes to the Committee's purposes to provide a comparison to APVMA's processes. We would be happy to continue these discussions with the Rural and Regional Affairs and Transport References Committee or our counterparts in Australia.

U.S. EPA's process for reviewing and reassessing the safety of pesticides:

The pesticide registration and registration review processes are under the broad authority of the following laws. These laws hold EPA accountable for its pesticide processes and outputs:

- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),
- Federal Food, Drug and Cosmetic Act (FFDCA),
- Food Quality Protection Act, of 1996 ,
- Pesticide Registration Improvement Act of 2003 (PRIA), and
- Endangered Species Act (ESA)

Under FIFRA, it is illegal to sell or distribute a pesticide unless it is registered by EPA. EPA registers pesticides based on sufficient scientific data for the agency to conclude that it can be used safely for the intended purpose, following approved label instructions and precautions. Under FIFRA, pesticide labels are legally enforceable; they bear the statement: "It is a violation of federal law to use this product in a manner inconsistent with its labeling." Such misuse can subject the applicator to civil or criminal penalties. FIFRA provides primary enforcement responsibility for pesticide use to the states. Each state has a lead agency (often the state department of agriculture) with primary responsibility for investigating and enforcing incidents involving the use of pesticides in the state.

All pesticides follow a standard registration and registration review process. EPA followed the standard protocol for generating a work plan, requiring data, reviewing open literature data, evaluating registrant submitted studies, completing risk assessments, and soliciting public comment.

As a federal agency, our funding is determined by Congress. EPA's Office of Pesticide Programs also collects PRIA fees from pesticide registrants. PRIA also sets decision review timelines so that EPA reviews and makes a registration decision in a timely manner. Additionally, PRIA authorizes EPA to collect maintenance fees from registrants to support registration review.

Like in all executive agencies, EPA employees are subject to the employee standards of ethical conduct issued by the U.S. Office of Government Ethics. These standards provide specific assurances to help guarantee impartiality. EPA employees maintain a high level of ethical conduct to maintain the public trust.

Furthermore, members of the FIFRA Scientific Advisory Panel are classified as "special government employees" and are similarly subject to ethical screening and training as required by the office of government ethics to ensure members do not have conflict of interest and can render impartial advice.

Public participation is vital to the effective registration and registration review of pesticides. All interested individuals and groups are equally welcome to participate in our multiple opportunities for public comment, which are established in the registration and registration review processes. For more information on how stakeholders can participate see the Public Participation Process for Registration Actions and the Opportunities to Participate in Pesticide Reevaluation.

Another way we ensure the inclusion of stakeholders in our scientific and policy decisions is by consulting our federal advisory committees. The Pesticide Program Dialogue Committee, in particular, is a representative federal advisory committee. Representative members are selected to represent a diverse group of stakeholders to provide feedback to EPA on various pesticide regulatory, policy, and program implementation issues. In selecting members, EPA will consider candidates from pesticide user, grower and commodity groups; consumer and environmental/public interest groups; farm worker organizations; pesticide industry and trade associations; state, local and tribal governments; federal government; academia; the general public; and public health organizations.

Transparency and independence policies:

EPA strives for transparency in our scientific analyses. Our science policies, guidance documents, and guidelines have been through peer review and public comments, and are publicly available. Our scientists develop independent, objective evaluations of studies sponsored by pesticide registrants and those available in the open scientific literature. Risk assessments and regulatory decisions are routinely published in a federal docket for public comment and EPA seeks feedback from the public on its scientific methodology and its proposed regulatory decisions. Public comments are reviewed and considered in decision-making. Our scientists routinely give presentations to the public and to other scientific experts. We also frequently meet with stakeholders (including industry, growers, non-governmental organizations, states) on numerous issues pertaining to pesticides. When necessary, EPA also holds publicly accessible Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) meetings to seek feedback and/or technical advice from independent experts. As part of this review process, all relevant documents and studies are accessible in a public docket.

EPA performs its own independent evaluation of available data to ensure that pesticides do not pose unreasonable risks to human health or the environment. Often the dataset is composed of hundreds of studies and consists of data from a variety of sources, including extensive human health, product chemistry, environmental fate, and ecotoxicity data from the pesticide producer, other pesticide companies, academia, and published scientific literature. The agency strives to use high-quality studies to inform risk assessment decisions.

Data collection:

Any company that registers pesticides in the U.S. under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) or seeks a tolerance (maximum legal residue in food) or tolerance exemption for a pesticide under the Federal Food, Drug, and Cosmetic Act (FFDCA) must conduct a broad suite of studies to meet the requirements of registration. These studies include product chemistry, product performance, human health, environmental fate, ecotoxicity, post-application exposure, spray drift, residue chemistry, and others. A complete list of required studies is available on EPA's website.

FIFRA gives EPA broad authority to establish or modify data requirements and timing for individual pesticide registration actions to achieve statutory and program objectives. Data requirements for pesticide registration actions are found in the Code of Federal Regulations at 40 CFR Part 158. These regulations give EPA substantial discretion to make registration decisions on the basis of what we determine to be the most relevant and important data for each action.

The National Academy of Sciences National Research Council (NRC) has encouraged the agency to move toward systematic review processes to enhance the transparency of scientific literature reviews that support chemical-specific risk assessments to inform regulatory decision making. EPA employs "fit for purpose" systematic reviews that rely on standard methods for collecting, evaluating, and integrating the scientific data supporting the agency's decisions. For the evaluation of the human carcinogenic potential of glyphosate, data were collected by searching the open literature and other publicly available sources (e.g., recent internal reviews, evaluations by other organizations). Internal databases were also searched for studies conducted according to Organization for Economic Cooperation and Development (OECD) test guidelines, Office of Chemical Safety and Pollution Prevention (OCSPP) harmonized test guidelines, and other pesticide test guidelines (OPP guidelines). A separate systematic review of the open literature was performed for hazard identification and characterization purposes to identify studies that could potentially impact the human health risk assessment.

Scientific approaches used to assess evidence:

EPA uses the same standard risk assessment procedure for all pesticides. See an overview of the Office of Pesticide Program's standard process for risk assessment on EPA's website. Each step in risk assessment (planning, hazard identification, dose-response assessment, exposure assessment, and risk characterization) follows standard criteria. Standard guidance for human health risk assessment for pesticides are followed for every case and are publicly available.

Similarly, EPA's standard process for conducting ecological risk assessment and standard guidance for ecological risk assessment are publicly available.

The agency strives to use high-quality studies when evaluating pesticide chemicals and considers a broad set of data during this process. This includes registrant generated studies, typically using OECD test guidelines, required under FIFRA, as well as peer-reviewed scientific journals and other sources, such as other governments and academia. All studies are thoroughly reviewed to ensure appropriate conduct and methodologies are utilized and that sufficient data and details are provided. This ensures that decisions are informed by the best science available.

Studies submitted to the agency are generally evaluated based on OECD, OCSPP, or OPP test guideline requirements to determine whether studies are acceptable for use in risk assessment and EPA's conclusions about individual studies are summarized in DERs. To evaluate open literature studies, criteria described in the 2012 OPP guidance for considering and using open literature toxicity studies to support human health risk assessment are followed. This guidance assists OPP scientists in their judgement of the scientific quality of open literature publications. More specifically, the document discusses how to screen open literature studies for journal articles/publications that are relevant to risk assessment, how to review potentially useful journal articles/publications and categorize them as to their usefulness in risk assessment, and how the studies may be used in the risk assessment. As with submitted studies, those deemed unacceptable are noted and subsequently excluded from evaluations. EPA uses a weight-of-evidence approach when integrating data from multiple sources to take quality, consistency, relevancy, coherence biological plausibility, and uncertainty into account. Application of weight-of-evidence analysis is an integrative and interpretive process routinely used by EPA and outlined in its risk assessment guidelines.

Furthermore, all final work products are subjected to multiple levels of internal peer review. This includes reviews of individual studies, hazard and exposure assessments, risk assessments, and any additional supporting documentation.

Glyphosate's review:

The glyphosate registration and registration review team is composed of more than two dozen staff with expertise in various disciplines, including toxicology, pharmacology, epidemiology, chemistry, biology, environmental fate, entomology, statistics, risk management, and communications.

EPA will follow the standard protocol when the registration review process reaches the regulatory decision-making phase for glyphosate. However, given the high level of public interest in glyphosate's reevaluation and the IARC's conclusion regarding glyphosate's cancer potential, additional steps were used for glyphosate to ensure transparency and scientific quality.

Following the IARC decision regarding glyphosate, the EPA Office of Pesticide Program's (OPP) Cancer Assessment Review Committee (CARC) conducted an independent review of the available data for its own reevaluation. Subsequently, a more comprehensive systematic review of studies submitted to the agency and available in the open literature was performed. All

relevant studies were then incorporated into the weight-of-evidence evaluation of the human carcinogenic potential of glyphosate, which was presented to the FIFRA SAP. The panel members were selected based on their knowledge of core expertise needed for the evaluation of the human carcinogenic potential, such as epidemiology, animal bioassays, and genotoxicity.

As part of the process with the FIFRA SAP, all supporting documentation was publicly available, which included full study reports, the agency's individual study reviews (data evaluation records, or DERs), and the agency's issue paper detailing the process and decisions undertaken to reach the conclusions based on a weight-of-evidence approach. The transcript to the glyphosate FIFRA SAP meeting is also available.

EPA's risk assessment for glyphosate was conducted independently of any other organization and the IARC decision did not influence EPA's conclusions. EPA's cancer classification for glyphosate is based on a weight-of-evidence evaluation in accordance with the agency's 2005 Guideline for Carcinogen Risk Assessment. The dataset considered by EPA included studies submitted for registration of glyphosate, as well as studies identified in the open literature as part of a systematic review. EPA also incorporated data that were not previously available into its evaluation. IARC only considers data that have been published or accepted for publication in the openly available scientific literature. As a result, IARC only considered a subset of the studies included in EPA's evaluation. EPA also did not use some studies that IARC incorporated into their evaluation because EPA did not believe the studies were appropriate for determining the human carcinogenic potential of glyphosate. For example, genotoxicity studies conducted in non-mammalian species (*i.e.*, worms, fish, reptiles, plants) were excluded from the EPA's evaluation because they were not considered relevant for informing the genotoxic risk in humans.

EPA is confident in its conclusion that glyphosate is not likely to be carcinogenic to humans. EPA's conclusion is consistent with other countries and regulatory authorities including the Canadian Pest Management Regulatory Agency, Australian Pesticide and Veterinary Medicines Authority, European Food Safety Authority, the European Chemicals Agency, German Federal Institute for Occupational Safety and Health, The Joint FAO/WHO Meeting on Pesticide Residues, the New Zealand Environmental Protection Authority, and Food Safety Commission of Japan.

EPA's draft human health risk assessment evaluated dietary, residential/non-occupational, aggregate, and occupational exposures. This included an in-depth review of the glyphosate cancer database, including data from epidemiological, animal carcinogenicity, and genotoxicity studies. All the evidence used, and EPA's weight-of-evidence approach is summarized in the human health draft risk assessment and associated documents.

In the draft ecological risk assessment, EPA used the most current risk assessment methods, and completed a comprehensive evaluation of the potential effects of glyphosate exposure on non-target organisms. Full details on the evidence used as well as the EPA's methods for estimating them, can be found within the ecological risk assessment.

For more information, read the draft risk assessments and supporting documents.

We are currently reviewing public comments received on the draft assessment and plan to publish the proposed interim registration review decision for glyphosate in 2019. The proposed interim registration review decision will outline any proposed mitigation measures to reduce risk, if any are needed.

Thank you again for reaching out to us. I hope you find this information useful in compiling your report. If you have further questions, please do not hesitate to contact me.

Sincerely,

Richard P. Keigwin
Director
Office of Pesticide Programs